



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE: October 18, 2005

FROM: William Freas, Ph.D. WLF
Chief, Scientific Advisors and Consultants Staff, CBER

SUBJECT: Conflict of Interest Waiver for Donna M. DiMichele, M.D.

TO: Sheila Dearybury Walcott, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

Through: Jenny Slaughter
Director, Ethics and Integrity Staff
~~Division~~ of Management Programs, OM
Office

I am writing to request a waiver for Donna M. DiMichele, M.D., a consultant to the Center for Biologics Evaluation and Research from conflict of interest prohibitions of 18 U.S.C. 208(a). Waivers under Section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. Because you are the appointing official, you have the authority to grant Dr. DiMichele a waiver under Section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which, to her knowledge, the employee, her spouse, minor children, or general partner; an organization in which she is serving as officer, director, trustee, general partner, or employee, or a person or organization with which she is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. DiMichele is a special Government employee and is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to her or to her employer.

The function of the Committee, as stated in its Charter, is to advise the Commissioner of the Food and Drug Administration in discharging responsibilities as they relate to assuring safe and effective biological products for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

Dr. DiMichele has been asked to participate in the November 3-4, 2005 meeting of the Blood Products Advisory Committee. During the meeting, the Committee will discuss and make recommendations on approaches to over-the-counter home-use HIV test kits, Alpha-1-Protease Inhibitor products, and a subcommittee report on the intramural research programs in the Office of Blood Research and Review, Center for Biologics Evaluation and Research.

Dr. DiMichele has reported that she is a member of the [REDACTED], a member of the [REDACTED], a member of the [REDACTED], and a member of the [REDACTED]. She does not receive any remuneration for her services. In addition, Dr. DiMichele is the PI on an unrelated contract with [REDACTED]. Previously untreated patients with Hemophilia A (PUPS); is a PI on an unrelated grant with [REDACTED] to study safety and efficacy [REDACTED] and a PI on an unrelated grant with [REDACTED] to study females with severe or moderate Hemophilia A or B.

Under Section 208, Dr. DiMichele is prohibited from participating in any matter affecting these interests, unless she receives a waiver. However, as noted above, you have the authority under 18 U.S.C. 208(b)(3) to grant a waiver.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. DiMichele that would allow her to participate in the discussions of the Committee. These discussions do not involve product approvals.

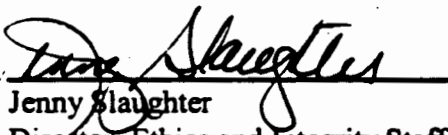
The waiver is also justified because the Committee has a special need for Dr. DiMichele's services because of her unique expertise, experience, and viewpoints with respect to the issues before the Committee. Dr. DiMichele is an internationally recognized clinician with expertise in the treatment of hemophilia and bleeding disorders. She is board certified in pediatric hematology/oncology. Dr. DiMichele has been an invited presenter at numerous national and international conferences and has many publications in her areas of expertise. Dr. DiMichele's expertise in hemophilia, Factor VIII, and the safety of blood derivatives will be invaluable to the Committee.

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Associate Commissioner for External Relations
Food and Drug Administration

For these reasons, I believe that Dr. DiMichele's participation in the deliberations of the advisory committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

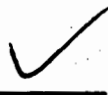
According, I recommend that you grant Donna M. DiMichele, M.D., a waiver that would allow her to participate in the discussions before the November 3-4, 2005, meeting and any other meeting where these interests are unrelated. I believe that such a waiver is appropriate because, in this case, the interests of Dr. DiMichele are not likely to affect the integrity of the services that the Government may expect from her.

CONCURRENCE:


Jenny Slaughter
Director, Ethics and Integrity Staff
Division of Management Programs, OM
Office

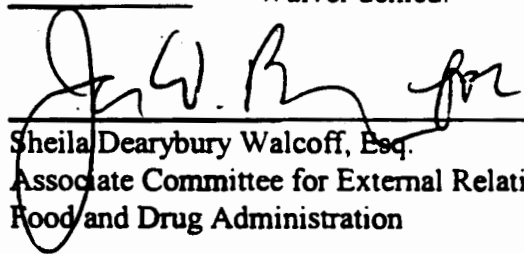
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Date

DECISION:



Waiver granted based on my determination, made in accordance with Section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

Waiver denied.


Sheila Dearybury Walcott, Esq.
Associate Committee for External Relations
Food and Drug Administration

10/31/05
Date